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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,154	12/10/2001	Ryusuke Nakagiri	2139.27	2545

5514 7590 06/18/2003

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EXAMINER
DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	4

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/010,154	Applicant(s) NAKAGIRI ET AL.
	Examiner Liliana Di Nola-Baron	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *39-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38 and 43-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National S application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3* .
4) ☐ Interview Summary (PTO-413) Pape
5) ☐ Notice of Informal Patent Applicatic
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-38 and 43-51, drawn to compositions comprising a plant of the family Saxifragaceae or an extract of the plant as an active ingredient, and a method of protecting or improving liver function in an animal, comprising feeding the animal with said compositions, classified in class 424, subclass 439.

   II. Claims 39-42, drawn to a method of screening for liver function protecting or improving agents, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different modes of operation, as the invention of Group I is directed to compositions and a method of treatment, whereas the invention of Group II recite a diagnostic method to test the efficacy or the toxicity of a substance. The inventions of Grou and Group II would be expected to have distinct functional, chemical and physical propertie evidenced by their divergent classification and process of using. Each of the inventions is capable of supporting a separate patent within the art. The test substance in the method o

Invention II can be isolated from a plant source other than a plant of the family Saxifragaceae, which is the active agent claimed in the compositions and method of Invention I.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Lawrence Perry, Attorney for Applicant, on May 28, 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-38 and 43-51. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 39-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 51 is objected to because of the following informalities: the word "food" in l is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-5, 7-15, 17-23, 25-30, 32-37, 43-49 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-5, 7-15, 17-23, 25-30, 32-37, 45-49 and 51 read on compositions comprising a plant of the family Saxifragaceae, and claims 43 and 44 recite a method comprising feeding an animal with compositions comprising a plant. The plant is found in nature and animals feed on plants from the family of Saxifragaceae. Birds, for example, open the berries of Gooseberry, Miccosukee of the Saxifragaceae family, to eat the seeds (See p. 10 in the article "Species Gooseberry, Miccosukee"). With respect to the form of the composition claimed in the instant application (food and drinks, feed, food and drink additive or feed additive), the leaves and fruits of the plants are natural forms of food, feed and food additives, and the juice in the fruit is a natural drink. Since Applicant does not claim any particular carrier, binder, homogenizing agent or any other conventional ingredient commonly used for the manufacture of food and drinks, feed, food additives and food additives, in the compositions and methods as claimed, hand labor or machinery are not required to produce compositions different from the natural plant. Consequently, the claims do not embody patentable subject matter as defined in 35 U.S.C. 101. MPEP 2105 provides several quotes from the Chakrabarty decision and summarizes: 5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . .". (See MPEP 2105, No. 5.). It is suggested that Applicant limits the invention to an extract isolated or purified from the plant to identify a product, which is not found in nature.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 8-13, 45-47 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokogawa et al. (JP410046142A).

The abstract of the Japanese patent discloses an extract of Saxifraga stolonifera obtained from the whole plant and teaches that the composition has uses in many fields, including foods. The protection or improvement of liver function claimed by Applicant is inherent to the composition. The patent meets the limitations of claims 1-3, 8-13, 45-47 and 51 of the instant application, as the prior art contemplates an extract of a plant of the Saxifragaceae family, specifically Saxifraga stolonifera, and its use in foods. Thus, the patent anticipates the claimed invention.

11. Claims 1-4, 7-14, 45-48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita (JP405056772A).

The abstract of the patent provides a tea comprising a mixture of a medicinal plant and Hydrangea serrata, and includes Saxifraga stolonifera among the medicinal plants used in the invention. The protection or improvement of liver function claimed by Applicant is inherent to the composition.

The patent meets the limitations of claims 1-4, 7-14, 45-48 and 51 of the instant application, as the prior art contemplates a drink comprising plants of the Saxifragaceae family, specifically

Saxifraga stolonifera and Hydrangea, as claimed by Applicant. With regard to the limitation of claim 7, that the composition is administered orally, a tea is administered orally. Thus, the patent anticipates the claimed invention.

12. Claims 1, 2, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamahara et al. (XP002220391).

The paper discloses Hydrangeae Dulcis Folium, obtained from the extract of Hydrangea macrophylla Seringe var. Thunbergii Makino, and teaches that the extract has cholagoic (bile-related) activities. The protection or improvement of liver function claimed by Applicant is inherent to the composition.

The paper meets the limitations of claims 1, 2, 4, 5 and 8 of the instant application, as the prior art contemplates Hydrangea Dulcis Folium, obtained from the extract of Hydrangea macrophylla Seringe var. Thunbergii Makino, as claimed by Applicant. Thus, Yamahara et al. anticipates the claimed invention.

13. Claims 1, 2, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamoto et al. (J. Prosthet. Dent.).

The article discloses Hydrangeae Dulcis Folium among the crude drugs, whose effects were investigated (See Abstract and Table I). Thus, the article discloses Hydrangeae Dulcis Folium, as claimed by Applicant, and meets the limitations of claims 1, 2, 4, 5 and 8 of the instant application. The protection or improvement of liver function claimed by Applicant is inherent to the composition. Thus, the abstract anticipates the claimed invention.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-3, 7-13, 17-21, 25-28, 32-35, 45-47 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Konishi (U.S. Patent 6,541,041). The filing date of the patent is January 27, 2000, which is before the invention by Applicant.

The patent provides crude drug extracts obtained from Saxifraga stolonifera (See col. 3, lines 31-54), thus it contemplates an extract of a plant, as claimed by Applicant in claims 1-3 and 8 of the application. The patent teaches that the extract can be made into solid or liquid pharmaceutical preparations for oral administration for treating animals and humans, and includes tablets, capsules, powders and liquids among the formulations for oral administration (See col. 6, lines 13-32). Thus, the patent contemplates oral administration of the composition, as claimed in claim 7, and the powders, tablets, capsules and liquids provided by the prior art are forms of drink and food or feed, as claimed in claims 9-13, 17-21, 45-47 and 51. With regard to the additive for foods and drinks claimed in claims 25-28, and the feed additive claimed in claims 32-35, the tablets, capsules, powders and liquids disclosed by the prior art are supplements, and the patent teaches that the extracts are used for treating both animals and humans (See col. 6, lines 30-32), thus the patent contemplates food and feed additives, as claimed by Applicant. The protection or improvement of liver function claimed by Applicant is inherent to the composition. The limitation "which is useful for the protection of liver function" in claims 10-11 and 18-19, and

the limitation "for the protection or improvement of liver function" in claims 45 and 51 are feature intended use, and feature intended use has no patentable weight in composition claims. The compositions disclosed by Konishi meet the limitations of claims 1-3, 7-13, 17-21, 25-28, 32-35, 45-47 and 51 of the instant application, as they contemplate oral compositions comprising an extract of Saxifraga stolonifera, a plant of the family Saxifragaceae, as claimed by Applicant. Thus, the patent anticipates the claimed invention.

15. Claims 1, 4, 7-11, 14, 17-19, 22, 25, 26, 29, 32, 33, 36, 45, 48 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson et al. (U.S. Patent 6,479,545). The filing date of the patent is September 30, 1999, which is before the invention by Applicant.

The patent provides compositions comprising herbals and herbal derivatives, such as herbal extracts and substances derived from plants and plant parts, such as leaves, flowers and roots, including Hydrangea (See col. 13, line 66 to col. 14, line 59). Thus, the patent contemplates a plant extract, as claimed by Applicant in claims 1, 4 and 8. Levinson et al. teaches that the compositions of the invention may be in the form of tablets, powders, elixirs, liquids, as well as in the form of animal feeds, cereals, cereal coatings, yogurts and foods, and the nutritional compositions may be administered orally (See col. 16, line 7 to col. 17, line 23), thus the patent contemplates oral administration of the compositions in the form of foods, drinks, feed, food additives and feed additives comprising a plant extract, as claimed in claims 7, 9-11, 14, 17-19, 22, 25, 26, 29, 32, 33, 36, 45, 48 and 51 of the instant application. The protection or improvement of liver function claimed by Applicant is inherent to the composition. The

limitation "which is useful for the protection of liver function" in claims 10-11 and 18-19, and the limitation "for the protection or improvement of liver function" in claims 45 and 51 are feature intended use, and feature intended use has no patentable weight in composition claims. The compositions disclosed by Levinson et al. meet the limitations of claims 1, 4, 7-11, 14, 17-19, 22, 25, 26, 29, 32, 33, 36, 45, 48 and 51 of the instant application, as they contemplate oral compositions comprising an extract of Hydrangea, a plant of the family Saxifragaceae, as claimed by Applicant. Thus, the patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 15, 23, 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamahara et al. (XP002220391) in view of Levinson et al. (U.S. Patent 6,479,545).

Yamahara et al. provides methanol extracts of Hydrangea macrophylla Seringe var. Thunbergii Makino, and teaches that the extract has cholagoic (bile-related) activity (See Introduction). Thus, the paper provides the teachings that extracts of Hydrangea macrophylla Seringe var.

Thunbergii Makino are known in the art and beneficially affect liver functions. The paper is deficient in the sense, that it is silent with respect to administering the plant extract to a subject, as claimed in claims 43 and 44, and does not provide dosage forms of the extract for oral administration, as claimed in claims 15, 23, 30, 37 and 49 of the instant application.

The teachings of Levinson et al. have been summarized above. The patent provides the teachings that compositions comprising an extract of hydrangea may be administered orally to humans and animals in the form of foods, drinks, feed, food additives and feed additives (See col. 14, lines 22-58 and col. 16, line 7 to col. 17, line 35). With regard to the animals recited in claim 44 of the instant application, Levinson et al. teaches that the composition of the invention can be administered to non-human mammals (See col. 9, lines 52-56). The livestock recited in claim 44 comprises mammals.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the extract of Hydrangea macrophylla Seringe var. Thunbergii Makino disclosed by Yamahara et al. in the form of food and drink, as claimed in claims 15 and 49, feed, as claimed in claims 23 and 49, additive for foods and drinks, as claimed in claim 30, and feed additive, as claimed in claim 37, as taught by Levinson et al., and to devise a method comprising feeding an animal with the compositions of the invention, as claimed in claims 43 and 44, to improve liver functions, as taught by Yamahara et al. The expected result would have been a successful oral nutritional composition of the extract of Hydrangea macrophylla Seringe var. Thunbergii Makino and a successful method for protecting or improving a liver function.

Because of the teachings of Yamahara et al., that extracts of Hydrangea macrophylla Seringe var. Thunbergii Makino are known in the art and beneficially affect liver functions, and the teachings of Levinson et al., that compositions comprising an extract of hydrangea may be administered orally to humans and animals in the form of foods, drinks, feed, food additives and feed additives, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing nutritional compositions, which are edible to humans and animals, and a non-aggressive method of protecting or improving liver functions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

18. Claims 6, 16, 24, 31, 38, 43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji Rebio (XP002220392) in view of Konishi (U.S. Patent 6,541,041).

Fuji Rebio discloses tannins purified from Saxifraga stolonifera and teaches that the tannins can be applied to the treatment of hepatitis B (a viral disease of the liver) in admixture with proper vehicles, including fillers and bulking agents, in the form of tablet, powder, granules and pill for oral administration (See Abstract). Thus, the paper provides the teachings that substances isolated from Saxifraga stolonifera may be used in oral dosage forms for the treatment of a liver disease. With regard to claims 6, 16, 24, 31, 38 and 50, the patent is deficient in the fact , that it does not specify how the plant extract is processed. With respect to claim 43 of the instant

application, Fuji Rebio is deficient in the sense, that it does not specifically teach that the compositions are administered to an animal.

Konishi provides crude drug extracts of Saxifraga stolonifera and teaches that water, ethanol or a mixed solution thereof is used as an extracting solvent (See col. 5, lines 4-51). Thus, with respect to claims 6, 16, 24, 31, 38 and 50 of the application, the plant extracts obtained by the prior art are obtained by adding a mixture of water and ethanol to the crude extract, rather than adding the alcohol to an aqueous extract of the plant, as claimed by Applicant. Applicant has not established the criticality of the two-step extraction process as compared to the one-step extraction process disclosed by the prior art, and there is no comparable example in the specification to demonstrate that the claimed extraction process provides some unusual and/or unexpected results. It appears to the examiner that the claimed extraction process does nothing additional to the compositions of the invention, especially in view of Applicant's disclosure that the extracts of the plants can be obtained by various methods of extraction (See p. 13 in the specification) and solvents can be used alone or as a mixture (See p. 14 in the specification), and the teachings of the prior art, that plant extracts of Saxifraga stolonifera can be obtained using a mixture of water and alcohol as an extracting solvent.

With respect to the step of feeding an animal with a plant extract, which is recited in the method claimed in claim 43 of the instant application, Konishi teaches that the plant extract can be made into solid or liquid pharmaceutical preparations for oral administration for treating animals and

humans, and includes tablets, capsules, powders and liquids among the formulations for oral administration (See col. 6, lines 13-32).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide extracts of saxifraga stolonifera using water and ethanol as extracting solvents, as taught by Konishi, and to devise a method comprising feeding an animal with compositions comprising extracts of Saxifraga stolonifera, as claimed in claim 43, to improve liver functions, by treating disorders caused by the hepatitis B virus, as taught by Fuji Rebio. The expected result would have been a successful oral composition of the extract of Saxifraga stolonifera and a successful method for protecting or improving a liver function. Because of the teachings of Fuji Rebio, that agents in the extracts of Saxifraga stolonifera are effective against the hepatitis B virus and thus beneficially affect liver functions, and the teachings of Konishi, that compositions comprising an extract of Saxifraga stolonifera are obtained by water and alcohol extraction and may be administered orally to humans and animals, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing nutritional compositions, which are edible to humans and animals, and a non-aggressive method of protecting or improving liver functions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

19. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji Rebio (XP002220392) in view of Konishi (U.S. Patent 6,541,041) as applied to claims 6, 16, 24, 31, 38, 43 and 50 above, and further in view of Fukunaga (U.S. Patent 5,525,340).

The teachings of Fuji Rebio and Konishi have been summarized above.

Fuji Rebio provides the teachings that substances isolated from Saxifraga stolonifera may be used in oral dosage forms for the treatment of a liver disease (See Abstract).

Konishi teaches that extracts of Saxifraga stolonifera can be made into solid or liquid pharmaceutical preparations for oral administration for treating animals and humans (See col. 6, lines 13-32).

The prior art is deficient in the sense, that it does not specify the animals, which may be fed with the plant extract of the invention.

Fukunaga provides antimicrobial compositions comprising hydrangea and creeping saxifrage (Saxifraga stolonifera) (See col. 1, line 60 to col. 2, line 65). Fukunaga teaches that the composition of the invention is of value as a food, supplement or additive for quasi-drug use and can be added to water tanks for aquarium fish (See col. 3, lines 27-39). Thus, Fukunaga provides the teachings, that compositions comprising plants from the family of Saxifragaceae can be fed to fish.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to devise a method comprising feeding animals, specifically fish, with compositions comprising extracts of plants from the family of Saxifragaceae, as claimed in claim 44, to improve liver functions. The expected result would have been a successful method for protecting or improving a liver function. Because of the teachings of Fuji Rebio, that agents in the extracts of Saxifraga stolonifera are effective against the hepatitis B virus and thus beneficially affect liver functions, the teachings of Konishi, that compositions comprising an extract of Saxifraga stolonifera may be administered orally to humans and animals, and the teaching of Fukunaga, that antimicrobial compositions comprising hydrangea and/or Saxifraga stolonifera may be used as food and fed to fish, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful in providing a non-aggressive method of protecting or improving liver functions comprising nutritional compositions, which are edible to humans and animals. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

20. Claims 1-38 and 43-51 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Liliana Di Nola Baron

June 16, 2003

Liliana Di Nola-Baron

Patent Examiner

AU 1615